

Report of the Governor's Advisory Board  
for  
The Virginia Biotechnology Initiative

RECOMMENDATIONS FOR A STATEWIDE  
COMPREHENSIVE AND COORDINATED  
STRATEGY FOR BIOTECHNOLOGY

THE FIRST STEPS:  
Building the Industry Base and Commercializing  
Current Technologies

Advisory Board Co-Chairs

The Honorable Michael J. Schewel, Secretary of Commerce and Trade  
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### Executive Summary

Pursuant to Executive Order Number 14 (2002) by Governor Mark R. Warner, establishing the Biotechnology Initiative, a Governor's Advisory Board of 44 members was constituted to develop recommendations for a statewide comprehensive and coordinated strategy for biotechnology.

During the Board's five meetings, held throughout the Commonwealth during August through October, 2002, testimony was heard from academic, government and industry experts covering all areas of biotechnology endeavor in the state, including university research, biotechnology start-ups, venture capitalists, community colleges, state and local economic development agencies, and other community and industry leaders from both within and outside of Virginia.

The Board has formulated a vision for the Commonwealth to become a globally recognized center for the growth and formation of the biotechnology industry, consistent with the strengths and competitive advantages of the Commonwealth's research universities, laboratories, healthcare institutions and industries. It sets a goal of having Virginia ranked among the top ten biotechnology states in the United States by 2010. Seventeen recommendations are described in this Report, covering four primary "foundational" areas:

- Access to Financial Capital

*These recommendations speak directly to the crucial need for capital at the seed and early stages of biotechnology companies. The amount of capital available to these start-ups correlates directly with the size of the biotechnology industry in a given state or region.*

- Human Capital

*These recommendations concern the necessity to attract and retain the brightest academic stars to Virginia's research universities – stars whose research activities will fuel the creation of new companies. They also suggest means by which a biotechnology workforce can be trained by community colleges and assisted by state-supported programs.*

- Facilities and Infrastructure

*These recommendations address the means by which the Commonwealth can assist in creating the specialized research facilities needed at its colleges and universities, develop incubators and "step-up" space in selected research parks, and attract service and support companies that are vital to growth of biotechnology in the state.*

- Intellectual Capital

*These recommendations are concerned with increasing the effort involved in moving intellectual property created at Virginia's research universities and laboratories into the marketplace. Not only must more financial resources be*

*expended in the evaluation and licensing of technologies, but the barriers to commercialization that exist within the Commonwealth, at all levels, should be removed.*

If implemented, these recommendations will set Virginia firmly on the road to becoming a full economic participant in the biotechnology revolution. The Board recognizes that, given the Commonwealth's current budget situation, some recommendations may need to be deferred. However, this Report will serve as a blueprint for implementations over time. The Board felt strongly that making the "right" recommendations is more important than pursuing a politically expedient course driven solely by current circumstances.

The title of this report: "THE FIRST STEPS: Building the Industry Base and Commercializing Current Technologies" suggests that this should not be construed as a comprehensive strategy for Virginia comparable to what Michigan and other states have already begun to implement. The time available to complete the initial report, together with the significant amount of material and testimony that the Board received, did not allow sufficient time to fully identify Virginia's comparative advantages and how the Commonwealth can differentiate itself as a "biotechnology state". Also, the strategies outlined herein do not address the fundamental investments that the Commonwealth will have to make in our "engines" of economic growth, our major research universities, if the state is serious about becoming a recognized center for the biotechnology industry. Thus, a final recommendation is made to continue the work begun by this Advisory Board for an additional 12 months, with the clear charge of developing a fully comprehensive and coordinated long-term statewide strategy for biotechnology. For the Commonwealth to achieve a globally competitive position, it will be necessary to build on both the foundational elements addressed in this report, and to make the long-term, strategic investments in the research institutions and initiatives, that will ultimately distinguish the Commonwealth.

### Introduction

Virginia is at a crossroads. Will the Commonwealth actively participate in the biotechnology revolution that is defining the 21<sup>st</sup> Century, or will Virginia be only a passive participant while other states and nations reap the benefits of the new companies, jobs and investments that are being created?

Virginia has an impressive array of assets that can stimulate and support a vibrant biosciences industry, including premier research universities, medical schools, federal and state laboratories, technology parks, incubators and healthcare systems. The Commonwealth has a large number of engineers, scientists and technology workers in its workforce and enjoys superior strategic location as a business center that has been proven for nearly 400 years. The diversity of Virginia's economy is one of its greatest attributes, ranging from more traditional sectors such as fishing, agriculture and mining, to high technology industries such as microelectronics, IT and biotechnology.

The competition from states, regions and countries around the globe that have targeted biotechnology and life science-related industries as part of their economic development strategies is rapidly escalating. Many state governments have made strategic long-term investments in

infrastructure, workforce development programs and incentives to grow and attract this industry which is expected to create large numbers of high-paying, technology-based jobs and companies. The Commonwealth of Virginia is in danger of falling behind the competition and, as experience has already shown, having promising biosciences companies that have started in Virginia lured away because the state lacks the comprehensive strategy necessary to compete successfully.

Pursuant to the signing of Executive Order Number 14 (2002) by Governor Mark R. Warner, which set forth the Biotechnology Initiative and established a Governor's Advisory Board, 44 members were appointed by Governor Warner in early August. A list of Board members is appended hereto as Appendix A. Subsequently, the Board held a total of five meetings around the Commonwealth (Richmond, Charlottesville, Blacksburg, Williamsburg, and McLean) in the 8-week period from August 23<sup>rd</sup> to October 16<sup>th</sup>.

One of the first orders of business for the Board was to define scope. There was concern that the term "biotechnology" might be construed in too narrow a fashion, and that the Board should address the full range of opportunities represented by biotechnology -- biopharmaceuticals, medical diagnostics, transgenics, biomedical devices, medical automation, medical informatics, bioinformatics, nanotechnology, bioremediation, biochemistry, biology and biophysics -- in short, any life science or healthcare field where the tools and technologies developed by biotechnologists are being employed. However, we chose to retain the single term "biotechnology" throughout the report with the understanding that it denotes this full spectrum of activities and opportunities.

Over the course of these five meetings, the Board heard testimony from 28 experts covering all areas of biotechnology endeavor – from university research to industry product development; from marine biology to biopharmaceutical manufacturing; from fundamental technology mining to seed and mezzanine funding; from new workforce development programs at community colleges to graduate research programs at the Commonwealth's major research universities; from start-up incubators to corporate research centers; from the use of incentives and other programs by the Commonwealth's economic development offices for attracting new biotechnology business to the use of methods employed in achieving the successes of the North Carolina biotechnology boom.

The Governor's Advisory Board has formulated a vision for the Commonwealth to be a full and equal economic participant in the biotechnology revolution. We offer an initial set of recommendations for the Commonwealth to follow in order to establish the state's competitive position. These recommendations are grouped under the four "foundational" areas of consideration that have proven to be the essential ingredients of strong bioscience clusters: (A) access to capital; (B) human capital; (C) facilities and infrastructure; and (D) intellectual capital. For each of these foundational areas, a Preamble frames the environment and issues and a set of Recommendations is set forth. The Board recognizes that each recommendation, if accepted and endorsed by Virginia, will have an impact on state policies. In addition, the Board recognizes that the Commonwealth's current budget situation may mean that some recommendations may need to await better economic times. Following each Recommendation is a Background and Rationale discussion, ending with a set of specific Implementation options and recommendations.

The recommendations of this report do not constitute, in their entirety, a comprehensive biotechnology strategy for the Commonwealth comparable to what Michigan and other states have already begun to implement. That is why this report is entitled “The First Steps: Building the Industry Base and Commercializing Current Technologies”. While the Commonwealth can and will benefit from steps to improve the “foundational elements” to build a biotechnology industry, we must also be careful not to take a shortsighted approach and deplete the “seed stock” needed to propel Virginia to a leadership position over the long term. Research universities in collaboration with our federal and state laboratories, are the “engines” of a future biotechnology economy. Strategies to invest in, and build upon, the individual and collective strengths of these drivers of a biotechnology industry must be considered equal in importance to these “first steps” if Virginia is truly serious. The Virginia Life Initiative is an example of the articulation of such a strategy.

Virginia Life was prepared in 2001 as a collaboration involving VaTech, UVA, VCU and GMU (see <http://www.innovationavenue.com/storage/PDF/biotech/virginialife.pdf> for a copy of the initiative). The Virginia Life initiative recommendations identify a number of areas where the Commonwealth is urged to make investments in order to build on the respective strengths of each institution to create a stronger, statewide life sciences consortium with the ultimate goal of creating new economic development activity in the life sciences. The Board stopped short of fully endorsing Virginia Life because of its significant multi-year cost which would be difficult to defend in today's budget environment, as well as the need to expand the initiative to include other research institutions and laboratories in the Commonwealth. The Virginia Life Initiative has already spawned the Virginia Bioinformatics Consortium (VBC), a current working example of where and how several Virginia research universities are collaborating using resources provided by the Commonwealth. The VBC has also identified a tangible example of an opportunity for Virginia to create a competitive market “niche” through creating a “Digital Patient Record” which is a proposed collaboration involving VCU, UVA, GMU and IBM.

There will be many opportunities for Virginia to create a leadership position and capitalize on our strengths employing a Virginia Life-type approach. By encouraging our research institutions, federal and state labs, and other unique resources to come together and inventory their strengths, we can identify strategic biotechnology investments that will create opportunities for establishing a leadership position. This is the next phase of work that must be undertaken by this Board, its successor(s) or through some other process. It will *only* be through such a strategic second-stage process, coupled with making the investments/changes in the four foundational areas, that Virginia will be able to achieve the vision articulated in the next section of this report, and thereby firmly establish Virginia as a center for research, development and delivery of the products and services that will mark the biotechnology revolution.

A GLOSSARY of terms is contained in APPENDIX B to this document.

## Vision

*Virginia will become a globally recognized center for the growth and formation of the biotechnology industry, consistent with the strengths and competitive advantages of the Commonwealth's research universities, laboratories, healthcare institutions and industries. By the year 2010, Virginia will be ranked among the top ten states in the U.S. in terms of the critical economic factors by which the industry is measured.*

## Recommendations and Implementation

### **A. ACCESS TO CAPITAL**

*Virginia needs a comprehensive array of funding vehicles and programs to support the growth of the biotechnology industry from the earliest stages through long-term stability, including private sector sources, institutional investment, and state programs which aid companies in assembling and preserving capital for fueling the growth of the companies.*

#### Preamble

The Board's analysis and recommendations concerning access to capital are based upon a number of key findings, as follows:

1. Access to capital is crucial: the amount of capital available correlates directly with the size of the biotech industry in a given state or region.
2. The need for capital is most crucial at the seed and early-stages because the potential sources and amounts of capital are the most limited at these stages, and there is a severe shortfall in availability for biotech. In particular, studies by such firms as Burrill & Company and Merrill Lynch have shown that less than 10% of venture capital investment goes into the biotechnology sector.
3. Although the primary need is for venture capital, angel investors can play a significant secondary role in providing the necessary capital, especially for seed and early-stage funding.
4. Today, little early-stage capital for biotechnology is available in Virginia, and the state will have to take special steps to make such capital available.

5. Many other states (including ones that already have far more funding available than does Virginia) have been implementing aggressive programs to mobilize venture capital. These state programs tend to be rather large. To use just a few examples: this year alone Pennsylvania invested \$60 million in three private VC funds (on top of \$100 million for three regional incubators); North Carolina invested \$42 million in VC funds (on top of \$40 million in complementary programs); and even West Virginia invested \$25 million in a half dozen private VC funds. Iowa has announced its intention to invest \$100 million, and Illinois is investing \$50 million. Maryland, Georgia and others have previously taken similar steps. All of these initiatives target biotechnology research and development.
6. Tax credits are another potential important source of financing for young bioscience companies.
7. Any new incentives and structures implemented to mobilize capital in Virginia should harness the private sector to the maximum extent possible, minimize or avoid any operational role of the state, incorporate as much leverage and selectivity as possible and mobilize existing biotech VC funds through assistance with due diligence.

## Recommendations

**Recommendation A-1. Establish a program to invest state (including university endowment) funds in one or more private venture capital funds, targeted at biotechnology, chosen through a competitive process.**

**Background and Rationale:** This model has worked quite well in a number of other states. It has quickly and effectively attracted experienced VC funds, established their presence in the state, and channeled their focus to the area of most crucial need – seed and early-stage funding for biotechnology. This model has also been quite effective in leveraging state resources. The applicant VC funds in other states typically already have other funding of \$20 million to over \$100 million that they, in essence, bring with them.

To be viable, though, any program of this type must offer a large enough state investment into VC funds to make it worth their time and attention to pursue. The state may choose as few as one fund (as Maryland did) or as many as half a dozen or more (as West Virginia did), but the bare minimum state investment appears to be about \$4-5 million *per fund* for several reasons. First, the management fee on the state's investment must be sufficient to cover the costs of establishing and maintaining an in-state office. A standard management fee of 2.5% on \$4-5 million amounts to \$100,000-\$125,000 per year. It is not feasible to staff and maintain an office on less. Second, the amount of investment must be sufficient to warrant re-channeling of a VC fund's time and attention to the kinds of investments that it (by definition) was not otherwise looking at and that are required as a condition of the state's investment. For sizeable, experienced VC funds, investment amounts of less than \$4-5 million are generally not sufficient to justify re-orienting the fund's focus and attention.

Once VC funds locate in the state, experience has shown that they end up looking at far more deals than they otherwise would, just because they happen to be there and it is easier to do so. In

addition, the venture business is highly relationship driven, and VCs tend to make investments as part of syndicates with other investors (including strategic investors such as pharma and other biotech companies). So, another major benefit – and leverage – to be obtained by bringing experienced VCs into Virginia will be that they bring a national network of relationships with them, and will be able to draw the attention – at least on a case-by-case basis – of a wide range of other investors from across the country.

**Implementation:** First, as quickly as possible, the state should establish a program similar to those implemented successfully by numerous competitor states (for example, Maryland), to make limited partnership (LP) investments in several venture capital funds that will begin making capital available for early stage biotechnology in Virginia. The state should allocate, or mobilize from sources such as the Virginia Retirement Fund, a total of at least \$25 million for these LP investments. At least half of the \$25 million should be invested in year one, and the remainder of the funds in year two. The investment size should be at least \$4-5 million per fund. The recipient VC funds should be chosen through a competitive process administered by the Department of [Business]. The VC funds should be required to maintain or establish an office somewhere in Virginia, and to commit to use best efforts to invest at least three times the amount of the state's LP investment in early stage biotechnology in Virginia.

Second, the state should also undertake an evaluation of whether to continue this direct-investment program after the first two years, or whether to transition to an indirect, investment-support program instead. Under the indirect approach, the state would establish a reserve fund or provide a limited state guarantee to cover half of the losses (if any) of Virginia institutional investors who invest in VC funds that, in turn, make significant early-stage biotechnology investments in Virginia

This program would not cover any losses of VCs themselves. It would cover only losses incurred by Virginia institutions as limited partner investors in VC funds – and would cover only half of those losses. Further, it would cover such losses only on investments in VC funds that maintained an office in Virginia and committed to use best efforts to make early-stage biotech investments in Virginia at least equal to the amount of covered investment by Virginia institutions. Guarantee fees or premiums could be charged, if desired.

The purpose of such an indirect (guarantee) approach would be to reduce or avoid the amount of cash required from the state, and increase the amount of investment funds mobilized. Institutional investors (retirement plans, endowments, insurance companies and others) are the primary funding source for VC funds, and in the long run can provide much larger amounts of capital than the state itself can ever do. A small percentage (but large dollar amount) of institutional portfolios is earmarked for high-risk investments but not much has not flowed into biotechnology to date.

Creating a reserve fund or a guarantee could provide a sufficient incentive to “unstick” private institutional funds. Covering only half of their losses would ensure that the institutional investors would still be careful in choosing well-qualified VC funds. This structure would also minimize the likelihood of the reserve fund or guarantees actually being drawn upon: it would mobilize VC

fund investments by multiple institutional investors, would cover them on a pooled basis, and would only have to pay out to the few of them that actually incurred losses.

**Recommendation A-2. Evaluate the existing programs and staffing of the Virginia Small Business Financing Authority (VSBFA) to determine their suitability for funding of early stage biotechnology companies. Modify program definitions and structures to fit biotechnology needs. Add or replace staff as needed to establish biotechnology expertise within the Authority.**

**Background and Rationale:** The VSBFA is already devoted to helping meet certain financing needs of small businesses. However, to date, the Authority has not had much activity relating to seed stage biotechnology companies. The Authority's programs currently may not be a good fit for biotechnology company needs. For example, to the extent that the VSBFA's programs consist of loans, they are not a good fit (even with generous loan terms) because biotechnology companies will not have any repayment ability for many years, and most equity investors will not invest unless all prior debt has been converted or discharged. Therefore, such programs would need to be adapted to allow the VSBFA funding to be in the form of equity or convertible debt, rather than straight loans.

**Implementation:** The recommendation can be implemented by the office of the Secretary of Commerce and Trade in consultation with biotechnology leaders in the Commonwealth.

**Recommendation A-3. Maintain or increase investment tax credit or other tax incentives for angel investments in biotechnology companies.**

**Background and Rationale:** Although secondary to venture capital (in amounts financed), angels are an important additional funding source for seed stage biotech. Tax credits to angels can be reasonably efficient in mobilizing angel capital, but provide only partial support of the angels' investments. Such tax credits also preserve selectivity -- angels are using their best judgment to channel funds to companies with better chances of success. In contrast, tax credits to biotech companies themselves, for R&D or equipment, do not preserve selectivity: they apply equally regardless of companies' chances of success, raising the costs and lowering the chances of success compared to tax credits for angel investors.

Virginia already provides tax credits for early-stage investors. Section 58.1-339.4 of the Virginia Code provides for an investment tax credit for equity or subordinated debt of a Virginia business with a maximum of \$5 million in annual revenue. The maximum annual statewide credit is \$5 million, with the per investor credit being 50% of the invested amount, not to exceed \$50,000. The equity or debt instrument must be held for five years or the credit amount must be repaid, with substantial penalties and interest. In 2001, HB 2466 was introduced, seeking to amend this Section by increasing the annual statewide credit from \$5 million to \$20 million, to increase the per taxpayer limit from \$50,000 to ten percent (10%) of the annual credit, and to reduce the holding period from five (5) years to two (2) years to avoid forfeiture.

As Legislative members of the Board made clear, tax credits (foregoing tax revenue to the state) are economically equivalent to outright expenditures, and have recently come to be viewed as such. Therefore, tax credits now must compete with other measures from a budget standpoint. Since tax credits will not achieve as much efficiency, selectivity or leverage as the programs proposed in Recommendations A-1 and A-2, tax credits should be considered only to the extent they may be additional to, and not in lieu of, Recommendations A1 and A2.

**Implementation:** This recommendation will require legislative action and can be shepherded by the Office of the Secretary of Commerce and Trade.

**Recommendation A-4. Identify and facilitate access to biotechnology experts who may assist investors with due diligence as paid consultants.**

**Background and Rationale.** Facilitating access to experts who can help existing VC funds (which have historically focused on IT and sectors other than biotechnology) evaluate technologies in the biotech sector may be sufficient to “unstick” some investment from these funds. Such assistance from experts will have to be prompt, effective and reasonable in cost, and may require some training or coaching of the experts on how to work with investors.

**Implementation:** CIT should create an on-line list or directory of such experts, updated quarterly, with a description of their expertise and the type of consulting or other involvement they are willing to have with investors. Include in the directory only experts who have been interviewed individually, and are willing and able to operate on the bases necessary (including rapid timeframes) for private investment deals. Display this directory (or at least links to the directory) on multiple applicable websites, including those of CIT, the VSBFA, the Virginia Economic Development Partnership, and each of the Virginia universities. Include biotechnology experts both in the private sector and in academia. Also include experts at Federal labs in Virginia, to the extent feasible.

## **B. HUMAN CAPITAL**

*Virginia can distinguish itself as the preferred location for biotechnology through investments in development of the human capital that will generate the intellectual property, have the ability to commercialize technologies and build companies, and fill the full range of biotechnology industry positions required by large and small biotechnology employers in the 21<sup>st</sup> Century.*

### **Preamble**

The human capital needed to sustain the growth of the biotechnology industry in Virginia will involve the full spectrum of workforce skills including Ph.D.s, laboratory technicians, manufacturing specialists and a full range of support personnel. Currently, Virginia's

biotechnology industry is in the early-stages of development; thus, there is less demand for support personnel and production skills and a continuing need for individuals who are involved at the discovery stage. This, however, will change with time as the industry matures.

Despite the outstanding quality of our institutions of higher education, the Commonwealth of Virginia significantly trails competitor states in several key biotechnology academic indicators that affect our ability to attract and retain a qualified workforce. Based upon data from the State Council for Higher Education in Virginia (SCHEV), there are three key interrelated areas that present a significant workforce challenge for the Commonwealth:

1. Focus of Research: Virginia's expenditures for academic research accounted for only 2% of the nation's total academic R&D expenditures in 2000. By comparison, academic R&D at the top four states comprised 33% of the nation's total expenditures. In addition, Virginia does not fare well when R&D expenditures are adjusted for economic productivity or state size. Based on R&D expenditures per gross state product, Virginia ranks 39<sup>th</sup>, placing in the bottom quartile of the nation. Based on R&D expenditures per capita, Virginia's colleges and universities ranked 37<sup>th</sup> nationally in 2000. Since basic research makes up nearly 70% of all academic research, if Virginia strives to be nationally competitive in academic research, it must support basic research at our colleges and universities.
2. Faculty Salaries and Recruiting and Retaining “Eminent Scholars”: Since the mid-1980's, the Commonwealth has only met its goal of reaching the 60<sup>th</sup> percentile of peer universities in terms of faculty salaries in two biennial budgets. In addition, each of the top ten U.S. research institutions employ on average approximately 49 members of the National Academy of Sciences and 24 members of the National Academy of Engineers. Virginia, however, is home to only 7 NAS members and 16 members of the NAE. Without competitive salaries and state-of-the-art equipment, it is difficult to attract and retain such renowned scholars.
3. Quality of Post-Graduate Education: Approximately 36% of students enrolled in the top ten research universities in the United States are engaged in post-graduate studies. In the Commonwealth, the average is only 27%.

## Recommendations

### **Recommendation B-1: Create an “Eminent Life Sciences Scholars” program, focused on biotechnology, for the Commonwealth’s research universities.**

**Background and Rationale:** To attract and retain the caliber of people required for a thriving biotechnology industry, the Commonwealth should focus resources on the “Eminent Scholars Program” at Virginia’s research institutions. It is well established that eminent faculty attract federal research dollars, leading in turn to additional graduate students and high prospects for the development of technologies for eventual commercialization.

Traditionally, Virginia has recognized the value of attracting and retaining star faculty. In 1964, the state created the Eminent Scholars Program to attract and retain nationally renowned teaching and research faculty. The program is a public-private partnership that encourages private giving

at Virginia's state-supported colleges and universities by providing state funds to match eligible endowment earnings. In 2001, the State Council on Higher Education in Virginia (SCHEV) estimated that Virginia's public institutions have provided supplemental funding to more than 500 faculty members across the state. Although the program was originally designed to be a dollar-for-dollar match on private contributions, state funding has fallen to as little as 41 cents on the dollar.

While the Advisory Board considers the merit of fully funding this program within the parameters of this Commission's charge, it is recommended the Commonwealth create a specific "Eminent Life Sciences Scholars" program. A major goal should be to increase the number of distinguished and accomplished biotechnology researchers at Virginia universities. The Commonwealth should utilize the Commonwealth Technology Research Fund (CTRF) or direct a part of either the general fund portion of the Tobacco Indemnification and Community Revitalization funds. Matching funds from the private sector as well as Virginia universities and institutes could also be employed.

A peer review commission would review potential recruits with the goal of identifying individuals whose contributions would propel that program into the top tier nationally.

This concept of targeting renowned life sciences faculty has been embraced by other states such as North Carolina, and during 2002 by Governor Roy E. Barnes of Georgia. Founded last year, the Georgia Cancer Coalition (GCC) invests a portion of the state's Tobacco Settlement proceeds in the program to strengthen cancer services and Georgia's higher education research programs. Their goal is to attract new cancer-related programs and businesses, nationally renowned scholars and to ensure that patients can receive state-of-the-art treatment within Georgia. Financial support from the State of Georgia for the Georgia Cancer Coalition is expected to be between \$300 million and \$400 million over the next 5 to 7 years. The state's intention is to leverage this amount with private sector funds, resulting in a total investment of approximately \$1 billion.

A key aspect of this recommendation is the recruitment of "Eminent Scholars" to lead advanced biotechnology research. For example, the GCC recently recruited a highly regarded stem-cell specialist to join the faculty at the University of Georgia. In addition to the funds used to recruit him, a foreign private sector biotech company moved their headquarters to Athens, Georgia and has provided more than \$1.5 million for an endowed professorship, approximately nine graduate students and additional technicians.

**Implementation:** Immediately direct \$8 million (\$2 million per endowed professorship, plus support funds as identified in Recommendation C-4 below) from the Commonwealth's Tobacco Indemnification and Community Revitalization and CTRF funds to recruit four "Eminent Life Science Scholars" to locate to Virginia. This fund could be organized under the Commonwealth's existing Eminent Scholars Program or through a separate biotechnology-focused non-profit entity (as yet undefined or identified) that would also solicit private sector foundation grants and other matching contributions.

**Recommendation B-2: The Commonwealth will ensure that faculty salaries will be at least at the 60<sup>th</sup> percentile of their national peer groups by 2006.**

**Background and Rationale:** In the mid-1980's, the Commonwealth established a policy of providing funding to ensure that average salaries among Virginia's teaching and research faculty are at the 60<sup>th</sup> percentile nationally of their peers. According to the State Council on Higher Education in Virginia, lack of state support, however, has resulted in the state reaching the 60<sup>th</sup> percentile goal in only two biennia – 1988-1990 and 1998-2000.

To be competitive, Virginia must ensure that our scholars are, at the very least, compensated at the national average. If the Commonwealth is unable to retain our existing scholars, it will be extremely difficult to attract new talent.

**Implementation:** To achieve the goal of maintaining at least the 60<sup>th</sup> percentile, the Commonwealth will need to increase compensation by approximately \$68 million per year. This figure is based upon data compiled by the State Council on Higher Education in Virginia from the AAUP 2001-2002 Salary Survey and includes a 4.6% annual salary increase rate for peers after FY2004.

**Recommendation B-3: Direct the Department of Business Assistance to maintain its recently lowered threshold of the number of jobs created for biotechnology businesses to be eligible for the Workforce Services program from 25 new positions created to 5.**

**Background and Rationale:** The Workforce Services Program administered by the Virginia Department of Business Assistance required until this past year a minimum of 25 new jobs created and a capital investment of \$1 million to be eligible for their workforce development training assistance. Because most biotechnology companies are usually no larger than 15 employees, and often as few as 5, it is extremely rare for a biotechnology-related business to be able to receive any state support for workforce training. DBA's current guidelines require only 5 new jobs and a \$50,000 investment for companies that apply before December 31, 2002.

**Implementation:** The Advisory Board recommends that the lowered thresholds for biotechnology-related companies be extended indefinitely.

**Recommendation B-4: Utilize state resources to support initiatives such as the Virginia Biotechnology Association's Biotech Summer Camp and the Fralin Biotechnology High School Teacher Training Initiative that promote biotechnology to students and teachers in the Commonwealth's K-12 system.**

**Background and Rationale:** Virginia wants to show that it is a progressive state that is serious about building a biotechnology-based economy. This will be measured by the depth of its commitment to workforce development and training. Careers in the biotechnology industry require exceptional dedication and educational training that must begin at an early age by encouraging young people to take the requisite advanced math and science courses required for

advanced education in the fields of interest. Too frequently, students develop an interest in biotechnology careers after they have graduated from high school, but lack the educational foundation that needed to begin in middle school and earlier. Through the leadership of the Virginia Biotechnology Association, J. Sargent Reynolds and John Tyler CC's, and the CIT in the Richmond area; and the Fralin Biotechnology Center at Virginia Tech in Blacksburg, pilot programs have been developed to provide "summer camp" opportunities for middle school students and teachers alike, to expose them to biotechnology and future career opportunities in the industry. A modest annual contribution by the state could expand this program to other areas of the Commonwealth. This would not only have the benefit of preparing Virginia's future biotechnology workforce, but would likely reinforce national/statewide educational performance goals as well.

**Implementation:** Virginia should expand the pilot "Biotech Bonanza" summer program (that has been offered in the Richmond area for the past two years through partnerships with VABio, the community colleges and local school systems) to 5 regions of the Commonwealth by 2004, ten regions by 2005 and statewide by 2007. An annual contribution of \$25,000 per region would be required, together with matching funds from industry, federal grants, the community colleges and other sources, in order to expand this program adequately.

**Recommendation B-5: Conduct an inventory of current community college-based biotechnology training programs, so that the community colleges system can rapidly deploy these training programs at additional locations in response to the requirements of research and development companies.**

**Background and Rationale:** For biotechnology companies, as for most knowledge-based companies, having a skilled and technically trained workforce is a key issue in a company's decision where to locate its business. Virginia's community colleges can provide this technical training on an efficient basis in a way that will enhance Virginia's attractiveness to bioscience companies by providing the necessary trained workforce. Some of Virginia's community colleges already provide training in these areas. However, better coordination and planning could produce a curriculum or set of curriculum that would allow several community colleges to develop strong core training programs in biotechnology. These programs should be modular in nature, so as to be easily duplicated at additional colleges as needed

**Implementation:** Conduct an inventory of current community college bioscience training programs, and identify ways to enhance those curricula based on inputs from industry as to their workforce needs and from universities as to preparation needed for further biotechnology education.

## **C. FACILITIES AND INFRASTRUCTURE**

*In order to both grow and attract the biotechnology industry, Virginia must provide the specialized research facilities needed at its colleges and universities, develop*

*incubators and step-up space in selected research parks and appropriate locations, and devise programs to ensure an adequate, available and affordable supply of specialized facilities for biotechnology companies in response to market demands.*

## Preamble

Biotechnology companies often require highly specialized and expensive space in order to develop the products or services that are being commercialized. Wet laboratory space has considerably different requirements from standard office space and can cost \$250-\$300/ft<sup>2</sup> for build-out, versus \$35-\$70/ft<sup>2</sup> for standard office space. Most speculative, multi-tenant buildings cannot accommodate the specialized requirements for wet labs because the mechanical/electrical systems are not sized to accommodate the loads that wet labs require. Further, the private sector is reluctant (and even unable) to finance the fit-out for wet labs and specialized space for biotechnology companies without a lengthy lease term that will fully amortize the improvements. Most early-stage biotechnology companies cannot project their space needs much beyond a few years, let alone the longer periods that most landlords would require.

There is a demonstrated shortage of wet lab space in the Mid-Atlantic area for biotechnology companies. States can also grow biotechnology clusters by strategically investing in contract manufacturing and the types of support facilities that biotechnology companies require. Virginia can accelerate the growth of the biotechnology industry in the Commonwealth through creating strategic programs that will encourage and support the construction of wet laboratory and specialized space across the Commonwealth.

The state can also encourage the growth of the biotechnology industry in Virginia by developing a network of biotechnology incubators and through strategic investment in the kinds of facilities that attract bioscience companies. Biotechnology is still a relatively young industry and the potential exists for the state to grow a significant component of its future industry by incubating start-up companies and working with the state's research universities to facilitate technology transfer and new business formation.

## Recommendations

**Recommendation C-1: The Commonwealth should establish a loan and lease guarantee program that will enable eligible public authorities to finance facility construction costs for small to medium-sized biotechnology companies in order to accommodate the growth of these companies from incubators and other early-stage environments, until such time that these private sector employers have reached the size and financial strength where traditional real estate providers are able to finance the specialized space needs they require.**

**Background and Rationale:** There is a two-fold problem that Virginia faces in providing adequate wet laboratory, research and office space for accommodating the growth of the biotechnology industry: 1) financing the specialized space which these types of companies need, the problem being the requirement for a long-term lease commitment from the company; and 2) financing the construction of the base ("shell") buildings, the problem being that the space needs

of these companies tend to grow on a graduated (but often rapid) basis, which means these early to mid-stage companies are not yet candidates for free-standing, build-to-suit facilities.

Early-stage companies can quickly outgrow incubator and start-up space as the companies secure funding and capital for expansion of their research activities. This frequently results in adding personnel and requiring larger or more specialized space in order to meet the milestone requirements associated with the source of funding. Yet such companies are not considered mature or stable companies by most traditional lending sources because they do not have an approved product(s) or sales and an operating history that enables them to enter into a traditional, long-term lease arrangement for their space. The cost of specialized space for these companies can frequently be in excess of \$250 - \$300 per ft<sup>2</sup>, and would usually require long-term (e.g., 10-15 year) leases in order for traditional sources to finance facility expansion.

The inability to meet the growing facility needs of these companies makes them especially susceptible to being approached by other states or locations that are willing to provide the space under reasonable lease terms. This creates the risk that Virginia may lose companies that it has made an investment to create through our research institutions, and incubate in research parks and other facilities.

A loan guarantee program for biotechnology facilities will require authorization and funding by the Virginia General Assembly and the Governor. Virginia has had experience with a somewhat analogous program for “shell building” construction in rural areas of the Commonwealth for attracting new companies and jobs. A loan guarantee program for biotechnology companies could be created through an appropriation, bonds, or by identifying a large pool of funds that do not have high turnover or liquidity requirements. Such a pool could function as a “backstop” for letters of credit or other means to upgrade the “rating” of financing methods that approved public authorities, created for economic development purposes, could use to finance the facilities for lease by private sector biotechnology companies. Such a program can be relatively low risk and not require a call on the funding sources if the program is appropriately structured and managed by entities that can assess the business risk of the early-stage biotechnology companies.

**Implementation:** 1). Virginia should create a program(s) that will provide loan guarantees for eligible public authorities to finance the construction and debt coverage for multi-tenant research, wet laboratory and office buildings that are designed to accommodate the specific needs of biotechnology companies as they grow out of incubators and early-stage space. The program should support up to \$25 million per year in base building construction and the debt coverage for the permanent financing or until such time as the public authority will assume the full risk for such facilities and repay any monies that the Commonwealth has had to pay on defaults or claims associated with the program; and

2). Using a similar (or the same program) provide for up to \$25 million per year in lease guarantees to eligible public authorities for the build-out of wet laboratory, research and office space for biotechnology companies up to 75 employees in total size and for a lease period not to exceed 10 years in length.

While there may be several methods to accomplish this goal, an innovative solution may be to consider issuing tax-exempt bonds through an entity like the VPBA and in turn, “grant” the proceeds to an “eligible public authority” which could then build the facilities and lease to small, private biotechnology companies. The rents collected would be retained by the public authority to set up a “revolving fund”, which could then be used to support the financing of future projects. This approach has several advantages, including the ability to issue tax-exempt debt, for which the debt service would be approximately \$1 million per year less than that of taxable financing (per \$10 million of debt issued). The grant from the state to the public authority would circumvent the problem of using tax-free debt for private purposes. The state’s one-time support for \$50 million worth of biotechnology facility construction (Implementation items 1 and 2 above) could then be leveraged to construct additional wet lab and research facilities in future years as the reserve fund grows from the rents, without having to ask the state for additional assistance.

**Recommendation C-2: The Commonwealth should develop a limited number of biotechnology incubators which are linked to and supported by business accelerators/support centers in key locations throughout the state, in order to facilitate technology transfer from research engines, incubate new biotechnology companies and create a critical mass of life science companies with established roots in Virginia.**

**Background and Rationale:** One of the best strategies for Virginia to become competitive in building a base of biotechnology companies is to “grow its own.” Biotechnology is still a young industry and unlike other business sectors, there are relatively few large companies in the marketplace that are looking to relocate or expand with major new investments and large numbers of jobs. Companies that begin at Virginia research universities and federal labs are started by scientists, and researchers, who have roots in the Commonwealth and are not prone to relocation as they grow and succeed, especially if other aspects of their needs can be met. Business incubators are a cost effective way to grow the industry because they provide flexible, high quality space and common amenities required by biotechnology companies at an affordable price. The most important requirement is for state-sponsored incubators to be linked to business accelerators/support centers employing “best practices” to help start-up and early-stage companies successfully deal with the business challenges that confront them.

Virginia has a limited number of life sciences incubators, located in Richmond, Charlottesville and Fairfax, although they are not all organized in the same manner with respect to linkage with technology transfer functions of research universities/research laboratories, and the type of business support functions which are allied. In order to fully expand the biotechnology industry in Virginia, a “network” of 8-10 incubators/accelerators should be built. A facility in the 10,000 ft<sup>2</sup> range (office + laboratories) could effectively serve to incubate an average of 4-5 companies per year, once fully leased, with a steady “pipeline” of prospects coming through technology transfer and independent start-ups. The construction costs, per facility, would be in the \$5-6 million range, and the annual business support acceleration function would require \$1 million per location for operating costs.

**Implementation:** The Commonwealth should support the establishment of at least one biotechnology incubator per year, giving priority to those locations that are close to research institutions and federal labs, are unserved/underserved, and that can demonstrate a strong flow of technology as measured by disclosure, patents and licensing activity. Incubators can be funded by grants, bonds, loan guarantees or master leases backed by the Commonwealth, and should be managed by experienced entities with the expertise to grow and graduate successful life science companies and keep the space filled with high quality prospects capable of becoming mature biotechnology companies.

**Recommendation C-3: Virginia should become the preferred location for manufacturing of new biotechnology products being created through breakthrough discoveries in biology, medicine and other aspects of healthcare, by attracting and supporting contract manufacturing facilities and the companies that specialize in serving the biotechnology, pharmaceutical and associated industries.**

**Background and Rationale:** The biotechnology industry is creating a large pipeline of future products that are the result of the exponential growth in information available through genomic mapping and proteomics leading to new drug targets, methods of treatment and diagnostic capabilities unheard of even a few years ago. All new products intended for human applications must be approved by the FDA, requiring significant testing and documentation on the part of the company. Most biotechnology companies do not possess the resources to invest in manufacturing processes, and they cannot afford the traditional pharmaceutical company model of vertical integration to supply the market with approved products. Accordingly, contract research and contract manufacturing organizations (CROs and CMOs, respectively) are important suppliers to the industry. Also, CROs and CMOs can serve as magnets for attracting small, mid-sized and even established biotechnology companies. Virginia's historical advantages as a manufacturing location (right-to-work state, wages, trained workforce, location/access, etc.) are applicable to the CMO industry and should be exploited. Contract manufacturing facilities, strategically located across the Commonwealth, could help Virginia to both compete and cooperate effectively with our neighbors, Maryland and North Carolina, while establishing a market leadership position.

**Implementation:** Virginia should move within the next 1-3 years to attract and establish a minimum of three recognized contract manufacturers for biopharmaceuticals in different locations in the Commonwealth through a combination of incentives and/or loan guarantee programs to enable the facilities to be constructed. The construction cost for an initial phase contract manufacturing facility which can later be expanded as the capacity is absorbed is \$30-\$40 million.

It is recommended that Virginia support the financing for construction of the facilities (if required in order to attract an experienced and qualified CMO to lease and operate the facility) through grants, loans, tax incentives or a loan guarantee program, structured similar to the description in the previous recommendation C-1. If a facility is strategically sited in the southern part of Virginia, along the North Carolina border, it might be able to capture business from the Greensboro/RTP areas where biotechnology companies located there have limited options for

contract manufacturing. Such a facility might be financed out of Tobacco Settlement monies. Facilities in Northern Virginia or Richmond would require an alternate source of financing, which may require the full faith and credit, or moral obligation, of the state, to support bonds that could be issued by a public authority, such as the Virginia Bio•Technology Research Park or the Virginia Resources Authority, for example.

Virginia should also devise an incentive program to attract qualified manufacturing companies to locate in Virginia through a “production grant,” similar to the Solarphotovoltaic and Semiconductor Manufacturing Grant programs. These incentives can be structured so that the payback is delayed by five years from the time the company begins operation, and is based on actual manufacturing “performance” (i.e., quantity of product produced) and the number of jobs that have been created and sustained on an annual basis, in order to qualify for the grant.

**Recommendation C-4: Build and sustain organizational infrastructure and physical facilities at state research institutions associated with the recruitment of “Eminent Life Sciences Scholars” as cited in Recommendation B-1.**

**Background and Rationale:** Attracting and recruiting top researchers in the life sciences, as articulated in the Human Capital section, Recommendation B-1 will contribute to the creation of new jobs and companies in the Commonwealth through licensing and commercialization of their research that will now be carried out in Virginia. Typically, top researchers in biotechnology and the life sciences have large research grants in their areas of specialization that they will bring when recruited. They also have “teams” of research fellows and assistants who follow these noted researchers and who must be recruited as a part of the entire “package”.

One of the difficulties that state research institutions face is not only the investment in the salaries of the noted researchers and research teams (addressed in Recommendation B-1), but also the cost of the facilities and equipment that must also be promised in order to recruit them. This usually involves retrofitting existing laboratory and research space in university facilities, as well as providing specialized and often expensive equipment, in order to induce these teams to relocate.

**Implementation:** A separate budget should be created to complement the “Eminent Life Sciences Scholars” recommendation in B-1 to assist the universities with the entire cost of the recruitment package. This budget should allocate up to \$2 million per Eminent Scholar to be recruited to the state’s research universities to facilitate the fit-out and conversion of space in university-owned labs and research buildings and to cover the cost of specialized equipment. If the program called for in B-1 were fully funded to recruit four eminent scholars per year, the corresponding appropriation that would be needed in order to fund this recommendation would be \$8 million per year.

## **D. INTELLECTUAL CAPITAL**

*Virginia must develop a culture of “harvesting” biotechnology intellectual property generated in Virginia colleges, universities, laboratories and institutions through the elimination of barriers for technology transfer, providing incentives to form Virginia-based companies, and strategic licensing of those technologies that will create new jobs and companies in biotechnology.*

### **Preamble**

During the course of debating intellectual property issues critical to a comprehensive biotechnology strategy for the Commonwealth, the Governor's Advisory Board concluded that important recommendations had already been clearly stated by the Intellectual Property (IP) Subcommittee of Virginia's Research and Technology Advisory Commission (VRTAC) in a November 2000 report (see [www.technology.state.va.us/ost/vrtac](http://www.technology.state.va.us/ost/vrtac) for a copy of the report). Unfortunately, it appears that little progress has been made in implementing these recommendations over the ensuing two years since they were made. Accordingly it seems prudent to capture and restate relevant recommendations in the light of the current environment, making modifications where appropriate.

In addition, the Board feels it is imperative that Virginia not only has “user friendly” technology transfer policies among its universities and research laboratories, but also should seek to make the ease of dealing with Virginia's universities a competitive advantage for the Commonwealth. Therefore, additional resources should be spent on commercialization of intellectual property developed in Virginia.

### **Recommendations**

**Recommendation D-1: The Commonwealth should create a “Virginia Biotechnology Commercialization Loan Fund” that can be used selectively by university technology transfer offices to assist in covering costs associated with evaluation of commercial potential, assessment of patentability, and other technology transfer issues. These funds will be applied only to biotechnology discoveries from those institutions where use of these funds will result in creating new jobs and biotechnology companies for Virginia and increase the rate of commercialization by Virginia institutions.**

**Background and Rationale:** The biotechnology industry worldwide is based on unusually close and synergistic relationships between companies and academic researchers. Many of the most significant commercial biotechnology inventions have originated in university research and, in turn, biotechnology companies often support research in colleges and universities that deepens their understanding of how best to extract economic benefit from such inventions. Start-up companies, including participation by the faculty or student inventors, are often the mechanism of choice for bringing university biotechnology inventions to market.

Additionally, biotechnology companies depend to an unusual degree on the protection of underlying inventions by means of patents rather than by trade secrets or other means.

Thus, it is especially important to the growth of the biotechnology industry in Virginia that the Commonwealth's universities are not only engaged in biotechnology research, but that they aggressively pursue appropriate patent protection on biotechnology inventions made by their faculty and students. Further, they must have a well-functioning system for making those patents available for use by industry under licenses to existing companies or through active participation in building new firms around them.

The Board is aware that the Commonwealth's universities are aggressively competing nationally for federal and private research funding in the life sciences that will yield important inventions in biotechnology.

The Board is also aware that the research universities in the Commonwealth have created the necessary policies, procedures and organizations to ensure that faculty inventions are disclosed and patent protection is considered and obtained as appropriate. Data provided to the Board by the universities indicates that on a number of performance measures the more senior institutions are performing well in this regard, and the other research institutions are moving up rapidly. Indeed, data from Virginia Tech, the University of Virginia, and Virginia Commonwealth University indicate that more than 50% of their current licenses (overall, not just in biotechnology) go to in-state businesses.

However, we are also aware that the responsible university entities are understaffed and underfunded, and this is the major bottleneck to the more rapid and effective commercialization of university biotechnology inventions in Virginia.

At present, the Commonwealth provides no direct financial support of the commercialization process at the universities, with the result that their intellectual property foundations are heavily dependent on income from immediate licensing of their patents to existing firms, often outside the Commonwealth. This lack of financial support means that a) not all patentable inventions are appropriately brought to the point of commercialization in a timely and efficient manner, b) negotiations with industrial partners over intellectual property agreements and licenses can take much longer than seems necessary or desirable to industry, c) the incentives for faculty to develop, disclose and participate in the patenting of inventions are weakened, and d) many patents are handled with an emphasis on cost saving rather than effective patent prosecution. Evidence from similar efforts elsewhere, including Virginia's own Carilion Biomedical Institute, indicates that overall technology commercialization performance can be enhanced significantly by greater investment in the technology transfer function. Unfortunately, while the financial "heavy lifting" has already been done by the funding of research, less than 1% of those research funds is typically being spent by universities in the critical technology transfer effort.

Most of the technology transfer operations at Virginia's universities, including their associated intellectual property foundations, have limited resources to cover the costs of market assessment, partner identification and review, and negotiation of licenses to inventions. Using technology

commercialization loan funds to cover these additional costs could make a major difference in how effectively Virginia's universities commercialize their life sciences technologies and in the quality of the interaction of those universities with partner companies.

The Board feels that the Virginia Biotechnology Commercialization Loan Fund is an excellent opportunity for the Commonwealth to distinguish itself competitively from other states promoting biotechnology growth. As noted above, the financial “heavy lifting” has already been done by the federal research. These Loan Fund dollars are needed to maximize a return from that research – a return that goes not only back to Virginia’s universities in the form of licensing income and equity, but also to the state’s coffers in the form new company formation and jobs created by the companies that are commercializing the research.

**Implementation:** The Board recommends creation of a permanent Biotechnology Commercialization Loan Fund with an initial investment of \$3 million in a fund to be administered by CIT. Universities or their intellectual property foundations could apply to the fund for loans of up to \$400,000 when it can be demonstrated that such funds are to be used for the evaluation of commercial potential, assessment of patentability, actual patenting and other technology transfer issues -- exclusively for biotechnology research. A strong preference should be given to funding those technology transfer activities aimed at startups to be located in Virginia. Loans provided under this program would be zero-interest loans to be repaid by the institution, triggered either by an exit event (i.e., the time that investors realize their investment – for example, an initial public offering) or within a period of time not to exceed seven years. The concept is to create the Fund as a revolving loan fund that is funded on an annual basis either by direct legislative appropriations or return of monies that have been loaned to the institution.

The Virginia Research and Technology Advisory Commission (VRTAC) should be charged with periodic evaluation of the Biotechnology Commercialization Loan Fund, and assisting CIT in monitoring the performance in creating new Virginia-based jobs and companies.

**Recommendation D-2: CIT should complete and fully implement a user-friendly, website based, statewide comprehensive biotechnology intellectual property database, including the Commonwealth’s research universities and federal laboratories.**

**Background and Rationale:** Several years ago the Center for Innovative Technology encouraged the Virginia universities to adopt a common database system for tracking inventions and issued patents (of all types) and offered to subsidize the purchase of the necessary software. At that time, the plan was to eventually use this platform to provide a central database of patents held by the Commonwealth’s universities. In addition to acting as a statewide database, appropriate software can help individual university patent offices manage their entire patent portfolio.

Recognizing their joint interests and shared challenges, the technology transfer officers from most of the Virginia universities formed a new “user’s group” in 1999 called the Academic Licensing Community of Virginia (ALCOVe). ALCOVe has become an important conduit for communication among technology transfer officers at Virginia institutions and for informing

companies interested in licensing opportunities. The ALCOVe website not only contains links to the university technology transfer offices, it also links to other useful intellectual property-related sites.

Completing the work started using the existing database and integrating that with the website and collaborative work already begun by ALCOVe, would be an excellent next step towards developing a more integrated IP effort throughout the Commonwealth.

**Implementation:** The President of CIT should be provided with sufficient resources to allow for the full implementation of the current (or appropriate other) system and the creation of a non-confidential database of life science technologies available for license. CIT should work with ALCOVe to ensure that the database contains appropriate information that will be most helpful to the IP offices and to companies interesting in licensing IP. In addition, CIT should be provided with sufficient resources to broaden awareness of the database's existence and, consequently, use access to the database and other intellectual property information.

Insofar as ALCOVe is an unstaffed "users group" it may be important to provide some infrastructure (e.g., webmaster services, secretarial support, funds for inter-institutional travel) to ensure that it will become an effective multi-institutional vehicle. A logical organization to provide such support is CIT. The Board requests that CIT seek funds to provide appropriate support for biolicensing activities of ALCOVe.

There is general agreement that existing university IP offices are operating near capacity and it seems unlikely that these offices will have sufficient manpower to spend large amounts of time in developing new mechanisms for inter-institutional cooperation and for maintaining common databases, etc. There is logic in creating a position for an individual who could devote time to creating, maintaining and extending a non-confidential database of biotechnology technologies available for license, and who could act as a resource for directing companies to appropriate institutional IP offices. Such an intellectual property coordinator could be located at CIT.

The Board recognizes that the exact work description for this coordinator position and the necessary time commitment requires further study. It will be important for those most knowledgeable about these issues, our institution's IP office directors, to take an active role in defining this position and determining whether it is part-time or full-time. Consequently we recommend that ALCOVe along with CIT be engaged to help develop the work description for the IP coordinator position, to be submitted to VRTAC by 1 February 2003. Further, funds to support this position should be allocated during the 2003 legislative session.

**Recommendation D-3: The General Assembly should amend the Virginia Conflict of Interests statute to give the university presidents the non-delegable power to extend waivers of employee conflicts of interest in the case of employee contracts for research or technology commercialization.**

**Background and Rationale:** Under Virginia law, it is a criminal offense for a state employee to enter into a contract with his or her employing agency if that employee will enjoy a benefit of

that contract of more than \$10,000 or if that employee has more than a 3% ownership interest in an outside entity entering into a contract with the employing agency. The conflict of interest statute is complex, confusing and potentially intimidating. It applies to all Commonwealth public university and college employees and officials.

The law provides that Boards of Visitors may extend waivers of such conflicts of interest for contracts for research or for the commercialization of university technology. This provision permits university faculty, if approved, to license university-owned technology to use in their external business or to use an external entity to enter in a research contract. This waiver process is typically embodied in formal university policy statements that must be approved by SCHEV. The power of the Boards to extend waivers cannot be delegated to university administrators or other officials.

The practical effect of the engagement of the Boards in the waiver process is that it can take one to six months for the preparation of a waiver request, submission of the request to a board, and board approval. Often, research and technology transfer decisions involving faculty may need to be agreed to within a matter of a few weeks, or less, rather than several months. The result is that complying with the formalities of the waiver process can become a significant practical and psychological barrier to faculty contracts, especially those that contemplate a faculty member engaging in a start-up enterprise based on his or her research results.

**Implementation:** The General Assembly should be asked to amend the statute to permit also the university presidents to give conflict of interest waivers in the same way that Boards of Visitors do now. This power to waive a conflict of interest should be granted to the respective university president, but not delegated to lower ranking officials. Furthermore, presidents should be required to notify their boards of any and all such waivers they give.

All other provisions of the conflict of interest law would remain unchanged.

**Recommendation D-4: VRTAC should organize and sponsor a workshop in the early fall of 2003 (and in subsequent years) to enhance awareness and understanding of biotechnology intellectual property opportunities and management throughout the Commonwealth and provide a forum for showcasing “best practices”. Such a workshop should include a major participation (*and sponsorship*) by members of industry, since they are primary “customers” and beneficiaries of improved IP policies and practices.**

**Background and Rationale:** The Board has found a widespread view that industry, government officials, university faculty, financial organizations and others are not well-versed in the management of intellectual property assets, in arranging for licensing of patents, and in the array of state, federal and institutional policies and practices that shape the context for more effective commercialization of intellectual property developed in Virginia's universities and federal laboratories.

The Board's view is consistent with that of the VRTAC IP Subcommittee report (issued in November, 2000); i.e., that the general lack of awareness and understanding, coupled with

certain aspects of state and institutional policy and practice, have led to substantial misunderstandings of the nature of past efforts--successful and unsuccessful--to commercialize university-based technology in Virginia.

An example of a recent success is the Carilion Biomedical Institute (CBI) process for commercializing sponsored Biomedical research at University of Virginia and Virginia Tech. In its first three years, CBI has demonstrated >5x improvement in the number of invention disclosures, patents filed, licenses taken and companies started per million research dollars, compared with the data published by the Association of University Technology Managers (AUTM). These results are based on ~100 research projects funded by a total of ~\$11 million (including university matching). The success derives from integrated engagement of medical, marketing, product development, IP and business expertise early and systematically in the research process, an effort involving a considerably higher investment in both technology transfer and commercialization than currently is made at the Commonwealth's universities. These results represent a "best practice" that could serve as a model for similar partnerships across the Commonwealth.

Indeed, several Commonwealth universities, notably Virginia Tech and the University of Virginia, have already begun to host intellectual property workshops where university faculty interact with intellectual property administrators and other outside interests (e.g., venture capitalists, legal counsel, etc.). The Board believes that a carefully planned and targeted statewide workshop would provide an important means by which to enhance IP awareness and understanding. The details of such a workshop can be found in the November 2000 VRTAC IP Subcommittee Report.

**Implementation:** The existing VRTAC IP subcommittee could organize and conduct the workshop. The direct assistance of staff at CIT or DIT would be needed as well. A meeting-planning firm could be contracted to handle all of the workshop arrangements.

## **E. A FINAL RECOMMENDATION**

The Board has put forth considerable effort and time to survey the challenges facing Virginia as it crafts a biotechnology strategy. However, an effort spanning less than three months, no matter how well conceived or executed, can not possibly provide the depth and clarity to the analysis and recommendations as a longer, more concentrated endeavor. Therefore the Board makes its final recommendation as follows:

**Recommendation:** The Governor should extend the life of the Board (or some variant thereof) for an additional 12 months, with the clear charge of developing a fully comprehensive and coordinated long-term statewide strategy for biotechnology that considers Virginia's competitive strengths, both today and in the future if/as investments are made, where the Commonwealth can develop competitive advantages in the life science industries of the 21<sup>st</sup> Century, and what the return on investment will be for the state, its businesses and citizens.

**Background and Rationale:** As noted above, a 2-3 month effort on such a large array of issues will not provide as thorough an analysis as Virginia deserves for its biotechnology strategy. Indeed, of the 41 states that have or are developing such strategies over the past four years (according to BIO), the typical effort has been between 10 and 18 months in duration and has involved literally hundreds of experts. The Board has succeeded in defining the four broad areas of challenge and has made a total of 16 recommendations – some of which, if implemented, will put Virginia on a “fast track” toward a coordinated strategy. Even though the areas of challenge are basically similar to what other states face, the fundamentals in Virginia are very different. Therefore, further in-depth work is needed for Virginia to have a truly first-class long-term approach that will put the commonwealth into the “Top 10” of biotechnology states. Such an effort will require a comprehensive inventory of Virginia’s biotechnology assets at its research universities, federal and state laboratories, health care systems and industries. The effort will also produce a coordinated in-depth strategy for how these assets can be harnessed and augmented to create a unique competitive capability that will enable the Commonwealth to declare itself a “biotechnology center” in the next decade and beyond.

**Implementation:** Any extension of the Board’s activities is purely at the Governor’s discretion. There are several options that the Governor could consider if he wants to extend the life and scope of this work, but to really underpin the long-term recommendations, some outside expertise could be beneficial. Many other states and regions have used outside consultants to do an independent assessment of strengths and to help develop a comprehensive strategy.

## APPENDIX A

### List of Governor's Advisory Board Members

#### Co-Chairs

The Hon.. Michael J. Schewel	Secretary	Dept. of Commerce & Trade
Dr. Brandon J. Price	Chairman	Virginia Biotechnology Association

#### Executive Director

Mr. Jerald Coughter	Industry Director	Virginia's Cntr. for InnovativeTech.
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#### Members

Mr. Jonathan Aberman	Partner	Fenwick and West LLP
Mr. Larry Alleva	Partner	Price Waterhouse Coopers LLP
The Hon. Fenton L. Bland	Delegate	Virginia's 63 <sup>rd</sup> District
Dr. Gene Block	VP & Provost	University of Virginia
Mr. Martin Briley	Executive Director	Prince William County EDA
Mr. Robert Capon	President & CEO	Adenosine Therapeutics
Dr. Swapan Chattopadhyay	Associate Director	Thos. Jefferson Natl. Accel. Facility
Dr. Raymond Cypess	President	American Type Culture Collection
The Hon. John S. Edwards	Senator	Virginia's 21 <sup>st</sup> District
Dr. Dennis Fisher	President and CEO	Carilion Biomedical Institute
Mr. Delma Freeman		NASA Langley Research Center
Dr. William Gibbons	Chair, OB/GYN	Jones Institute/EVMS
Mr. Daniel Gonzalez	Senior VP	USI Real Estate Advisors LLC
Ms. Dianne Hardison	Domestic Mktng. Dir.	Fairfax County EDA
Mr. Mark Herzog	Executive Director	Virginia Biotechnology Association
Mr. David Hula	Vice President	Renwood Farms, Inc.
Dr. James Kenimer	President	Biologics Consulting Group
Mr. Mark Kilduff	Executive Director	Virginia Economic Dev. Partnership
The Hon. Joe T. May	Delegate	Virginia's 33 <sup>rd</sup> District
Dr. Donald McAfee	Founder & CTO	Aderis Pharmaceuticals
Mr. Patrick McGarrah	Plant Gen. Manager	Eli Lilly and Company
Dr. Mark McNamee	VP and Provost	Virginia Tech
Dr. Alan Merten	President	George Mason University
The Hon.. W. Tayloe Murphy	Secretary	Dept. of Natural Resources
The Hon. George Newstrom	Secretary	Dept. of Technology
Dr. James Pearson	Deputy Director	Consolidated Laboratory Services
Ms. Linda Powers	Managing Director	Toucan Capital Corporation
Dr. Jerry Rubin	VP and Director	Howard Hughes Medical Institute
Mr. R. Carter Scott	Partner	McGuire Woods LLP
Mr. Sudhakar Shenoy	Founder and CEO	Information Mgmt. Consultants Inc.
Mr. Knox Singleton	President and CEO	INOVA Health System

Mr. Robert Skunda	President and CEO	Virginia Biotechnology Res. Park
Dr. Eugene Trani	President	Virginia Commonwealth University
The Hon. John C. Watkins	Senator	Virginia's 21 <sup>st</sup> District
The Hon. Vivian E. Watts	Delegate	Virginia's 39 <sup>th</sup> District
Mr. Hugh Wellons	Partner	Flippin Densmore Morse & Jessee
The Hon. Belle Wheelan	Secretary	Department of Education
Mr. Joseph Williams		Tobacco Grower
Mr. Greg Wingfield	President	Greater Richmond Partnership
The Hon. Jane Woods	Secretary	Dept. of Health & Human Resources
Dr. L. Donelson Wright	Dean and Director	Virginia Institute of Marine Science

## APPENDIX B

### Glossary of Terms

**Angel Investors:** These investors are private individuals that make investments in a company in exchange for equity ownership. Angel investors typically include family members, friends, associates and high net worth individuals looking for alternative investments.

**Biotechnology:** The use of biological processes to solve problems or make useful products. The terms “Life Sciences” and “Biosciences” are analogous.

**Bioinformatics:** The science of informatics as applied to biological research. Informatics is the management and analysis of data using advanced computing techniques. Bioinformatics is particularly important as an adjunct to genomics research because of the large amount of complex data this research generates.

**Biopharmaceuticals:** Medicines made by biological processes rather than by chemical synthesis. Many medicines developed using recombinant DNA techniques are termed biopharmaceuticals. Biopharmaceuticals are often also referred to as biologics, biological therapeutics, biotherapeutics and biotech drugs.

**CIT:** Virginia's Center for Innovative Technology was created by the General Assembly of Virginia in 1984 as a nonprofit organization designed to enhance the research and development capability of the state's major research universities. CIT has three main goals: 1) Enhancing federal research funding to Virginia's colleges and universities and industry. 2) Commercializing intellectual property from universities and laboratories and growing entrepreneurial companies. 3) Promoting technology-based economic development.

**Contract Manufacturing Organization:** Biotechnology companies that lack internal manufacturing capabilities contract companies in this sector to make significant supplies of their therapeutic products. Companies in this sector often offer services and volume capabilities ranging from small amounts, for pre-clinical research and development, to larger volumes necessary for clinical trials purposes and commercialization.

**Contract Research Organization:** Drug development requires specific skills and precise studies that extend beyond the research capabilities of some biotechnology companies. In order to meet these needs, companies may seek to outsource clinical-and even pre-clinical-research to specialized organizations, called Contract Research Organizations (CRO).

**Early Stage Funding:** Early stage or “Start-up” financing is sought by companies completing product development and initial marketing. Companies may be in the process of organizing or they may already be in business for one year or less, but have not sold their product commercially. Usually such firms will have made market studies, assembled the key management, developed a business plan and are ready to do business.

**Intellectual Property:** An intellectual property is any product of the human intellect that is unique, novel, and unobvious and has some value in the marketplace. It is protected in the form of patents, trademarks, service marks, trade names, trade secrets and copyrights.

**Limited Partnership:** A partnership comprised of one or more general partners who manage business and who are personally liable for partnership debts, and one or more limited partners who contribute capital and share in profits but who take no part in running business and incur no liability with respect to partnership obligations beyond contribution.

**Mezzanine Funding:** Third-Stage or Mezzanine Financing is provided for major expansion of a company whose sales volume is increasing and that is breaking even or profitable. These funds are used for further plant expansion, marketing, working capital, or development of an improved product.

**Seed Stage Funding:** Seed Stage is a relatively small amount of capital provided to an inventor or entrepreneur to prove a concept and to qualify for start-up capital. This may involve product development and market research as well as building a management team and developing a business plan, if the initial steps are successful.

**Shell building:** This is generally any building not designed to be a complete structure, but contains floors, walls, and roof. A Shell Building may contain certain HVAC, plumbing, and/or electrical work. A Shell Building cannot receive a Certificate of Occupancy until Tenant Improvement plans and construction are complete.

**Start-up Incubators:** An incubator is an enterprise that is set up to provide office space, equipment, and sometimes mentoring assistance and capital to new businesses that are just getting started. (The term is familiar in poultry farming, where an incubator is a specially equipped home for baby chickens.) Business incubators are set up by universities, non-profit groups, and increasingly by public sector economic development organizations.

**Start-up Financing:** This is provided to companies completing product development and initial marketing. Companies may be in the process of organizing or they may already be in business for one year or less, but have not sold their product commercially. Usually such firms will have made market studies, assembled the key management, developed a business plan and are ready to do business.

**Technology Transfer:** Technology transfer is a principal avenue for the movement of research results from the University to private companies so that products can be developed and commercialized based upon this new knowledge. These results may take the form of inventions, discoveries, processes, techniques, devices, and substances, both physical and biological.

**Venture Capital:** Venture capital is defined as the classic investment in the illiquid equity securities of a privately held business. Classic venture capital funds are managed by institutions (usually limited partnerships) that are staffed by full time professionals. Venture capital funds are motivated solely by the goal of producing capital gains and (less often) current returns on the securities in which they invest.

**VaBIO:** The Virginia Biotechnology Association is the 220-member statewide trade group that represents and promotes the scientific and economic impact of the life sciences industry in the Commonwealth of Virginia. VaBIO was founded in 1992 and is headquartered at the Virginia Bio-Technology Research Park, in Richmond, Virginia.

**Wet Laboratory:** A room used for laboratory application, research, and/or training in research methodology that requires special-purpose equipment (e.g., bench space, sinks, fume hoods) and/or special purpose utilities (e.g., piped services) that enables that room to be used for staff and/or student experimentation or observation.